

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Guidance for Prioritization of Pre-pandemic and Pandemic Influenza Vaccine

AGENCY: Office of the Secretary, Department of Health and Human Services

ACTION: Notice

SUMMARY: Influenza viruses have threatened the health of animal and human populations for centuries. A pandemic occurs when a novel strain of influenza virus emerges that has the ability to infect and be passed between humans. Because humans lack immunity to the new virus, a worldwide epidemic, or pandemic, can ensue. Three human influenza pandemics occurred in the 20th century. In the U.S., each pandemic led to illness in approximately 30 percent of the population and death in between 2 in 100 and 2 in 1000 of those infected. It is projected that a modern pandemic, absent effective control measures, could result in the deaths of 200,000 to 2 million people in the United States alone. Extensive information on federal government strategic and implementation plans for pandemic flu is available at <http://www.pandemicflu.gov>.

A critical part of the United States Government (USG) strategy to control the spread of a pandemic and reduce its health and societal impact is through the use of vaccines. The U. S. Government is working toward a goal of expanding domestic influenza vaccine surge capacity for the production of pandemic influenza vaccines for the entire population within six months of a pandemic declaration. However, at the beginning of a pandemic, the scarcity of pre-pandemic influenza vaccine and pandemic influenza vaccine (which could include up to two doses) will require that the limited supply be prioritized for distribution and administration. Pre-pandemic vaccine refers to influenza vaccine that is produced against a virus strain that is believed to have pandemic potential and is maintained in a national stockpile. Depending on what influenza strain actually causes the pandemic, stockpiled pre-pandemic vaccine may provide some protection. Total quantities of pre-pandemic vaccines will be limited.

Accordingly, the federal government has initiated a process to provide guidance to assist State and local governments, communities, tribal and territorial governments and the private sector in defining groups that should be considered for priority access to scarce vaccine. Guidance will be drafted by a federal interagency task force that will seek information and advice from relevant individual stakeholders, a public engagement process in selected communities across the country, and through this Request for Information (RFI). The federal government plans to issue draft guidance resulting from this process for public comment before finalization.

With this RFI, the Department of Health and Human Services (HHS) requests input from the public on considerations in developing guidance for prioritization of the distribution

and administration of both pre-pandemic and pandemic influenza vaccines based on various pandemic severity and vaccine supply scenarios. Specifically, HHS is seeking input on pandemic influenza vaccine prioritization considerations from all interested and affected parties, including but not limited to public health and health care individuals and organizations, as well as those from other sectors of the economy including, for example, travel and transportation, commerce and trade, law enforcement, emergency management and responders, other critical infrastructure sectors and the general public. Previous reports relating to pandemic influenza vaccine prioritization issues are available at <http://www.pandemicflu.gov>.

DATES: Responses should be submitted to the U.S. Department of Health and Human Services on or before 5:00 p.m., EDT, January 18, 2007.

ADDRESSES:

Instructions for Submitting Comments: Electronic responses are preferred and may be addressed to PandemicFlu.RFI@hhs.gov. Written responses should be addressed to U.S. Department of Health and Human Services, Room 434E, 200 Independence Avenue, S.W., Washington, D.C. 20201, Attention: Pandemic Influenza Vaccine Prioritization RFI. A copy of this RFI is also available on the PandemicFlu.Gov website and at <http://www.aspe.hhs.gov/PIV/rfi>. Please follow instructions for submitting responses.

The submission of written materials in response to the RFI should not exceed 25 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. Any information you submit will be made public. Consequently, do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

Public Access: Responses to this RFI will be available to the public in the HHS Public Reading Room, 200 Independence Avenue, S.W., Washington, D.C., 20201. Please call (202) 690-7453 between 9:00 a.m. and 5:00 p.m. to arrange access. The RFI and all responses will also be made available on the HHS website at PandemicFlu.Gov.

For Further Information Contact: Dr. Ben Schwartz, Office of Public Health and Science, (404) 639-8953.

SUPPLEMENTARY INFORMATION

Influenza viruses have threatened the health of animal and human populations for centuries. A pandemic occurs when a novel strain of influenza virus emerges that has the ability to infect and be passed between humans. Because humans lack immunity to the new virus, a worldwide epidemic, or pandemic, can ensue. Three human influenza pandemics occurred in the 20th century. In the U.S., each pandemic led to illness in

approximately 30 percent of the population and death in between 2 in 100 and 2 in 1000 of those infected. Extrapolating from experience in prior pandemics, it is projected that a modern pandemic, absent effective control measures, could result in the deaths of 200,000 to 2 million people in the United States alone.

The goals of the federal response to an influenza pandemic include to: (1) stop, slow, or otherwise limit the spread of the pandemic to the United States; (2) limit the domestic spread of the pandemic and mitigate the disease, suffering, and death; and (3) sustain infrastructure and mitigate impact to the economy and functioning of society.

A critical part of the United States Government strategy to control the spread of a pandemic and reduce its health and societal impact is through the use of vaccines. The U.S. Government is working toward a goal of expanding domestic influenza vaccine surge capacity to ensure the production of pandemic vaccines for the entire population within six months of a pandemic declaration. However, at the beginning of a pandemic, the scarcity of pre-pandemic and pandemic vaccine will require that the limited supply be prioritized for distribution and administration.

The Homeland Security Council *Implementation Plan for the National Strategy for Pandemic Influenza* requires that HHS in coordination with the Department of Homeland Security (DHS) shall identify lists of personnel and high-risk groups who should be considered for priority access to medical countermeasures, including pre-pandemic and pandemic influenza vaccine. Priority recommendations will reflect the pandemic response goals of limiting mortality and severe morbidity; maintaining critical infrastructure and societal function; diminishing economic impacts; and maintaining national security. Limiting transmission may also be an objective.

To accomplish this task a federal interagency working group has been established to: (1) recommend priority groups for pandemic influenza vaccination as guidance for State, local, and tribal pandemic planning; and (2) recommend priority groups for vaccination with pre-pandemic vaccine as guidance for State, local, and tribal pandemic planning. The working group is co-chaired by HHS and DHS and includes members representing other federal agencies. The working group is soliciting information from individual stakeholders in a series of meetings. In addition, a series of public engagement meetings will be held across the country to gather further information. This RFI provides an additional opportunity to inform the pandemic vaccine priority development process. In addition, the interagency working group's draft guidance and recommendations will be published in the Federal Register for a public comment period before being finalized.

Priorities for vaccine use will vary based on pandemic severity as well as the vaccine supply. In a situation where a very limited vaccine supply exists, it will be necessary to narrowly target and efficiently use the available vaccine. With greater availability, it may be feasible to expand priority groups and consider strategies to limit disease transmission. With respect to pre-pandemic vaccines, prioritization must consider the limited available

supply and the likelihood that protection will only be partial, depending on how close the pre-pandemic vaccine matches the circulating pandemic virus. Because no single priority list is appropriate for all scenarios and because significant uncertainty is involved, federal guidance will be developed for multiple contingencies.

Information Requested

For the purpose of developing pandemic influenza vaccine prioritization guidance, HHS requests input from the public on priorities for allocation of both pre-pandemic and pandemic influenza vaccines based on various pandemic severity and vaccine supply scenarios. HHS is interested in receiving comments on factors that should be considered in order to provide guidance on priority groups for pre-pandemic and pandemic vaccines to best achieve national pandemic response goals. As described earlier, the goals of the federal response to an influenza pandemic include to: (1) stop, slow, or otherwise limit the spread of the pandemic to the United States; (2) limit the domestic spread of the pandemic and mitigate the disease, suffering, and death; and (3) sustain infrastructure and mitigate impact to the economy and functioning of society. HHS is particularly interested in receiving responses to the following questions:

- What objectives, principles, strategies, criteria, assumptions and rationales should be considered in pandemic vaccine prioritization determinations?
- What is the relative importance of the three goals described above and what are the associated implications for vaccine prioritization?
- Which population group(s) should have priority for receiving pre-pandemic vaccine? Which should have priority for receiving pandemic vaccine? What is the rationale?
- How can fairness, equity, efficiency and related principles be reflected in the determination of priority groupings for receipt of pre-pandemic or pandemic vaccine?
- For priority groups, how should vaccine be allocated, distributed and administered? Who (federal, State or local authorities) should determine when and how the vaccine is distributed and administered?

Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in pre-pandemic and pandemic vaccine prioritization. Some examples of these organizations include but are not limited to the following:

- State and local governments
- Advocacy groups and public interest organizations
- State and local public health departments
- Vaccine manufacturing industry, distributors and related organizations

- Health care professional societies and organizations
- Police, law enforcement and public safety organizations
- Trade and labor organizations
- Emergency management and first responder organizations
- Chambers of Commerce and other business representatives
- Public utilities
- Other critical infrastructure sectors
- General Public

Date: December 8, 2006

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